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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,424	01/22/2004	William J. Carroll	000309-00053	1421
76317	7590	01/24/2008		
BLANK ROME LLP 600 NEW HAMPSHIRE AVENUE, NW WASHINGTON, DC 20037			EXAMINER STOKLOSA, JOSEPH A	
			ART UNIT 3762	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/761,424	Applicant(s) CARROLL ET AL.	
	Examiner Joseph Stoklosa	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 15-22 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 15-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. Claims 1-8 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US 2001/0031999) in view of Reiss (US 5,324,317).
4. In regards to claims 1 and 15, the Carter discloses an electrical stimulator for the treatment of pain (see for example paragraphs 2, 57, 58, Figure 2), comprising an interferential current generator that is capable of generating interferential alternating current output (see for example paragraphs 12 and 13), by using common sine wave generators (see for example paragraphs 63 and 77, and Figure 8), with a base frequency of at least 1 KHz (see for example paragraph 12) that are capable of being

positioned at locations proximate to a patient's spinal cord and other locations (see for example paragraphs 36, 38, 41, 53 and 58). Further in regards to claims 1; Carter discloses a beat frequency, which is defined as difference between the feed signals (paragraph 36), however; Carter does not specifically disclose the use of at least two pair of implantable electrodes.

5. Reiss teaches that it is known to use at least two pairs of electrodes in interferential current treatments as set forth in Col. 2, line 27-38, for providing the predictable result providing optimization of the stimulation at the center. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Carter with the use of at least two pairs electrodes since such a modification would provide the system with the predictable result of providing optimization of the stimulation at the center.

6. Carter in view of Reiss discloses the claimed invention but fail to teach that the two pairs of electrodes would be implanted. Examiner considers the implantation of the at least two pairs of electrodes to be obvious to one having ordinary skill in the art, since such a modification would provide the system with a method for achieving deeper stimulation of tissue, as well as a more aesthetically pleasing system for the patient.

7. In regards to claims 2 and 16, Examiner takes the position that the Carter reference teaches of a pulse generator that generates digital signal pulses and the use of a digital signal processor (see for example paragraphs 63 and 75). Or in the alternative, Examiner take the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by

Carter to include a pulse generator that generates digital signal pulses and a digital signal processor, since these components are well known in the art to provide efficient and effective stimulation.

8. In regards to claim 3 and 17, Carter teaches of the use of pulse generator that generates digital signals (see for example paragraphs 63 and 75). Or in the alternative, similar to claim 2, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Carter to include a pulse generator that generates digital signals; since it is well known in the art that digital signals can be used to provide efficient and effective stimulation. Further, Carter does not specifically teach of the use of a field-programmable gate array; however, Examiner takes the position that the use of field-programmable gate arrays are well known in the art and it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Carter to include a field programmable gate array, since field programmable gate arrays are known in the art to enhance digital signals.

9. In regards to claim 4 and 18, Carter teaches of the use of a beat frequency that does not exceed 250 Hz (see for example paragraph 36).

10. With regard to claims 5-7 and 19-21, Carter in view Reiss disclose the claimed invention except for stimulation voltage and pulse width parameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Carter in view of Reiss with a voltage of 11 volts maximum and a pulse width of 210 microseconds, since it has been held that where the

general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233] and/or since it has been held that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ (Please see MPEP 2144.05).

11. In regards to claim 8 and 22, Carter does not specifically teach of the use of two quadripolar lead; however, Examiner takes the position that the use of quadripolar leads are well known in the art and it would have been obvious to one having ordinary skill in the art to modify the system as taught by Carter to include quadripolar leads, since quadripolar are well known in the art to provide effective and efficient stimulation.

Response to Arguments

12. Applicant's arguments filed 4/19/2007 have been fully considered but they are not persuasive.

13. Applicant argues that Carter teaches away from the use of multiple pairs of electrodes by discloses only a single return electrode. Carter does not teach away from multiple returns. Carter actually acknowledges the possibility of multiple pairs as seen in fig. 8. Carter shows return electrode 98 for channel 1, and a second optional channel with return electrode 102. Further Reiss teaches that it has been well known to use multiple electrode pairs.

14. Applicant also argues that there would be no motivation to have implanted electrodes, and that any motivation to implant the electrodes would be impermissible

hindsight reasoning. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

15. Further, it is well known in the medical art to implant devices for various reasons such as the need for prolonged therapy due to a chronic ailment. Additionally, Applicant acknowledges that previous well known implantable stimulation systems are known in the art (specification, page 3). In light of the numerous motivations to combine, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the electrodes implanted in order to provide the predictable result of achieving an aesthetic less obtrusive design.

16. Moreover, King (US 6,505,078) teaches the use of a fully implantable system that teaches implantation to also provide deeper stimulation and in effect a third dimensional field of stimulation.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Stoklosa whose telephone number is 571-272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/761,424
Art Unit: 3762

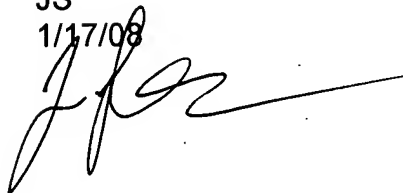
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Joseph Stoklosa
Examiner
Art Unit 3762

JS

1/17/08



GEORGE R. FERNANDEZ
1/22/08